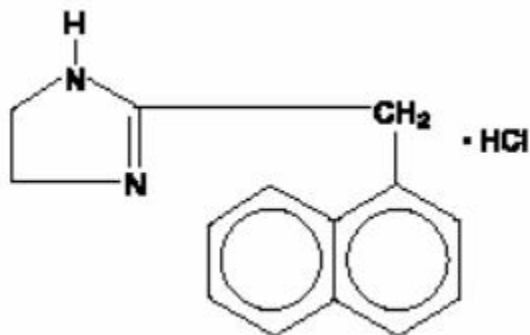


NAPHCON - naphazoline hydrochloride solution

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DESCRIPTION

NAPHCON® FORTE (Naphazoline Hydrochloride Ophthalmic Solution USP), 0.1% is a sterile preparation. Naphazoline HCl, an ocular vasoconstrictor, is an imidazoline derivative sympathomimetic amine. It occurs as a white, odorless crystalline powder having a bitter taste and is freely soluble in water and in alcohol. The active ingredient is represented by the structural formula:



$C_{14}H_{14}N_2HCl$

MW=246.74

Chemical name:

2-(1-naphthylmethyl)-2-imidazoline monohydrochloride

Each mL contains: Active: Naphazoline Hydrochloride 0.1%. **Preservative:** Benzalkonium Chloride 0.01%. **Inactives:** Boric Acid, Sodium Chloride, Potassium Chloride, Edetate Disodium, Sodium Carbonate and/or Hydrochloric Acid (to adjust pH), Purified Water. DM-00

The solution has a pH of 5.5 to 7.0.

CLINICAL PHARMACOLOGY

Naphazoline constricts the vascular system of the conjunctiva. It is presumed that this effect is due to direct stimulation action of the drug upon the alpha adrenergic receptors in the arterioles of the conjunctiva resulting in decreased conjunctival congestion. Naphazoline belongs to the imidazoline class of sympathomimetics.

INDICATIONS AND USAGE

NAPHCON® FORTE (Naphazoline Hydrochloride Ophthalmic Solution USP), 0.1% is indicated for use as a topical ocular vasoconstrictor.

CONTRAINDICATIONS

Contraindicated in the presence of an anatomically narrow angle or in narrow angle glaucoma or in persons who have shown hypersensitivity to any component of this preparation.

WARNINGS

NOT FOR INJECTION – FOR OPHTHALMIC USE ONLY. Patients under therapy with MAO inhibitors may experience a severe hypertensive crisis if given a sympathomimetic drug. Use in children, especially infants, may result in CNS depression leading to coma and marked reduction in body temperature.

Remove contact lenses before using.

PRECAUTIONS

General

For topical ophthalmic use only. Use with caution in the presence of hypertension, cardiovascular abnormalities, hyperglycemia (diabetes), hyperthyroidism, infection or injury.

Information for Patients

Patients should be advised to discontinue the drug and consult a physician if relief is not obtained within 48 hours of therapy, if irritation, blurring or redness persists or increases, or if symptoms of systemic absorption occur, i.e., dizziness, headache, nausea, decrease in body temperature, or drowsiness.

To prevent contaminating the dropper tip and solution, do not touch the eyelids or the surrounding area with the dropper tip of the bottle. If solution changes color or becomes cloudy, do not use.

Drug Interactions

Concurrent use of maprotiline or tricyclic antidepressants and naphazoline may potentiate the pressor effect of naphazoline. Patients under therapy with MAO inhibitors may experience a severe hypertensive crisis if given a sympathomimetic drug. (See WARNINGS.)

Pregnancy Category C

Animal reproduction studies have not been conducted with naphazoline. It is also not known whether naphazoline can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Naphazoline should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether naphazoline is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when naphazoline is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established. See "WARNINGS" and "CONTRAINDICATIONS."

ADVERSE REACTIONS

Ocular: Mydriasis, increased redness, irritation, discomfort, blurring, punctuate keratitis, lacrimation, increased intraocular pressure.

Systemic: Dizziness, headache, nausea, sweating, nervousness, drowsiness, weakness, hypertension, cardiac irregularities, and hyperglycemia.

DOSAGE AND ADMINISTRATION

Instill one or two drops in the conjunctival sac(s) every three to four hours as needed.

HOW SUPPLIED

NAPHCON® FORTE (Naphazoline Hydrochloride Ophthalmic Solution USP), 0.1% is available in 15 mL in DROP-TAINER® dispenser.

NDC 0998-0079-15.

Storage: Store at 8° - 27°C (46° - 80°F).

Caution: Federal (USA) law prohibits dispensing without prescription.

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